APPENDIX E

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

BIOGEN, INC., GENZYME CORPORATION, and ABBOTT BIORESEARCH CENTER, INC., Plaintiffs, v. THE TRUSTEES OF COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK, Defendant.	CIVIL ACTION No. 03-CV-11329 (MLW)

AMENDED COMPLAINT

Introduction

1. In 1983, nearly twenty years ago, defendant The Trustees of Columbia University in the City of New York ("Columbia") obtained a patent on a recombinant DNA technology called "cotransformation," a process for inserting foreign DNA into a host cell to produce certain proteins. In 2002, two years after the expiration of that patent and two related patents, Columbia obtained yet another patent on its cotransformation technology, and it is now attempting to use that patent in an illegitimate effort to extend its patent monopoly for another seventeen years. Plaintiffs bring this action for a declaration that Columbia has no lawful right to receive royalties from its licensees, including plaintiffs, based on its newly-issued cotransformation patent, because that patent is invalid and unenforceable.

2. Columbia's first cotransformation patent issued in August 1983. In 1987 and 1993, Columbia obtained two additional patents claiming substantially the same invention. All three patents originated from a single patent application filed by Columbia on February 25, 1980,

and all three patents were based upon the same experimental research described in that application. Because the United States Patent and Trademark Office ("Patent Office") determined that the second and third of Columbia's cotransformation patents claimed obvious variants of the first patent, and thus constituted impermissible "double-patenting," the Patent Office required Columbia to disclaim any rights in those patents extending beyond the expiration date of the first issued patent. As a result, all three patents expired the same day, August 16, 2000.

3. Columbia licensed its cotransformation patents to over thirty biotechnology companies and received hundreds of millions of dollars in royalty payments from those companies before the patents expired in 2000. In that year, Columbia mounted a widely criticized campaign to obtain special legislation from Congress extending the term of its original cotransformation patent by fifteen months, the result of which would have been a $100 million windfall for Columbia in the form of additional royalty payments from its licensees. Congress soundly rejected Columbia's effort. Accordingly, all three patents expired that year, and Columbia's cotransformation inventions entered the public domain.

4. Unbeknownst to Congress and the public, however, Columbia was at the same time prosecuting still more patent applications on its cotransformation technology. Columbia filed these applications in 1995, but had delayed prosecuting them through a variety of dilatory tactics. When Columbia's lobbying effort failed, Columbia refocused its efforts on its still pending patent applications. Through this strategy, Columbia found an alternative means to extend the life of its patent monopoly, not just for the fifteen months Columbia had requested unsuccessfully from Congress, but for seventeen years. By misleading the PTO about the claim scope of its earlier cotransformation patents, Columbia obtained for itself on September 24, 2002

a ***fourth*** cotransformation patent, with a term extending all the way to 2019, based on the ***same*** research described in the ***same*** 1980 patent application that had given rise to the first three cotransformation patents. Columbia then demanded royalties on this new patent from the companies that had licensed the earlier cotransformation patents. Because that patent is invalid and unenforceable, as explained below, this Court should grant declaratory and injunctive relief preventing its enforcement against plaintiffs.

Parties

5. Plaintiff Biogen, Inc. ("Biogen") is a Massachusetts corporation with its principal place of business in Cambridge, Massachusetts. Biogen has been engaged in biotechnology research for over twenty-five years. As a result of this research, Biogen has developed and now markets AVONEX® (Interferon beta-1a), the world's leading treatment for relapsing forms of multiple sclerosis, and AMEVIVE® (alefacept), a complex bioengineered molecule for the treatment of certain kinds of chronic psoriasis. In 1993, Biogen entered into a license agreement ("Biogen license agreement") with Columbia to obtain rights to use the cotransformation technology that Columbia patented. Since that time, Biogen has paid more than $35 million to Columbia under the Biogen license agreement. Biogen has also entered into a variety of other agreements with Columbia, including research collaborations and license agreements.

6. Plaintiff Genzyme Corporation ("Genzyme") is a Massachusetts corporation with its principal place of business in Cambridge, Massachusetts. Genzyme was founded in 1981 and is also a pioneer in the biotechnology industry. Genzyme is dedicated to developing drugs and other products to treat patients with certain rare genetic disorders and other serious debilitating diseases. Genzyme has developed innovative treatments for lysosomal storage disorders, rare and progressive genetic conditions caused by missing enzymes. Genzyme has developed and commercialized CEREZYME® (imiglucerase), the only available enzyme replacement treatment

for Type 1 Gaucher disease and THYROGEN® (thytotropin alpha) for use in thyroid cancer testing. Genzyme recently received FDA approval for FABRAZYME® (agalsidase beta) for the treatment of Fabry disease and ALDURAZYME® (laronidase) for treatment of MPS I (Mucopolysaccharidosis type-I). Genzyme is also the exclusive distributor of Biogen's AVONEX® in Japan.

7. Genzyme has entered into a variety of agreements with Columbia, including research collaborations. Columbia has also licensed certain screening technology (SAGE™, or serial analysis of gene expression) from Genzyme. In 1994, Genzyme entered into a license agreement ("Genzyme license agreement") with Columbia to obtain rights to use the cotransformation technology that Columbia patented. Genzyme has paid almost $25 million to Columbia under the Genzyme license agreement.

8. Plaintiff Abbott Bioresearch Center, Inc. ("Abbott Bioresearch") is a Delaware corporation with its principal place of business in Abbott Park, Illinois. Abbott Bioresearch conducts research, development, and manufacturing of its products in Worcester, Massachusetts. Abbott Bioresearch researches and develops new treatments for autoimmune disease, transplant rejection, and cancer, including the research and development of fully human monoclonal antibodies as therapeutic agents. Abbott Bioresearch manufactures a variety of biological products, including HUMIRA™, a fully human monoclonal antibody approved by the U.S. Food and Drug Administration in 2002 for the treatment of rheumatoid arthritis.

9. On June 1, 1995, Abbott Bioresearch's predecessor, BASF Bioresearch Corporation ("BBC") entered into a license agreement (the "BBC license agreement") with Columbia to obtain rights to use the cotransformation technology that Columbia patented. On March 2, 2001, Abbott Laboratories acquired Knoll Pharmaceuticals Company ("Knoll"),

including Knoll's subsidiary BBC. BBC thereafter changed its name to Abbott Bioresearch Center, Inc., and Abbott Bioresearch succeeded BBC as licensee under the BBC license agreement.

10. Defendant Columbia is a New York non-profit corporation with a principal place of business in New York, New York. It is the owner by assignment of United States patents 4,399,216 ("'216 patent"), 4,634,665 ("'665 patent"), and 5,179,017 ("'017 patent"), which it licensed to plaintiffs under the Biogen, Genzyme, and BBC license agreements (jointly, "License Agreements"). In addition to entering into the License Agreements with plaintiffs, under which it has accepted approximately $60 million dollars originating from Massachusetts, Columbia has also directed substantial and regular communications to plaintiffs in Massachusetts concerning the License Agreements and the '216, '665, and '017 patents. In 1993, Columbia brought suit to enforce the '216, '665, and '017 patents against a third party in this District. Columbia is the owner of recently issued United States patent 6,455,275 ("'275 patent").

Jurisdiction and Venue

11. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202. Also, because the amount in controversy exceeds $75,000, and the action is between citizens of different states, the Court has jurisdiction under 28 U.S.C. § 1332(a)(1).

12. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c).

Facts

A. Columbia's Original Cotransformation Patent Application

13. In the late 1970's, Richard Axel, Michael H. Wigler, and Saul J. Silverstein, scientists at Columbia University, carried out research on methods of inserting genes that code for certain proteins into the DNA of certain types of eukaryotic host cells. (Eukaryotic cells have a discrete nucleus, as distinguished from procaryotic cells, which are principally bacteria and

lack a structurally discrete nucleus.) Specifically, the Columbia scientists conducted experiments in cotransformation, a process of altering the genotype of a eukaryotic host or "recipient" cell by inserting into the cell *both* (a) a gene that codes for a desired protein and (b) a gene that codes for a "selectable marker." A selectable marker is a gene the expression of which confirms that the cell has been successfully transformed. For example, certain types of selectable markers may make a cell resistant to substances or conditions that would ordinarily kill the cell. A researcher can infer that this type of selectable marker has been incorporated into the cell's nuclear DNA if the cell survives in such hostile conditions. If the selectable marker has been incorporated into the host cell's nuclear DNA, it is likely that the cell has also incorporated the gene coding for the desired protein.

14. After conducting experiments concerning the cotransformation of certain types of mouse host cells with certain types of genes, Axel, Wigler, and Silverstein filed a patent application in February 1980. This application, serial no. 06/124,513, ("'513 application") assigned to Columbia, issued (after amendment) as the '216 patent on August 16, 1983. The '216 patent had 73 claims, broadly covering (a) processes for cotransforming cells, (b) processes for producing and recovering protein from a cotransformed cell, (c) processes for detecting cotransformed cells, and (d) cotransformed cells. It had a term of 17 years from the date of issuance, meaning that it would expire on August 16, 2000.

15. The research that led to the '216 patent was funded by the National Institutes of Health ("NIH"). NIH granted title to the invention to Columbia, but only upon certain conditions. Among these was the condition that any license "shall include adequate safeguards against unreasonable royalties and repressive practices. Royalties shall not in any event be in excess of normal trade practice."

B. Columbia's "Submarine" Patent Applications

16. Shortly before the '216 patent issued in 1983, Columbia filed a continuation application, serial no. 06/522,408 ("'408 application"). A continuation application is one that relies on the same disclosure, or specification, as an earlier, or "parent" application (in this case, the '513 application that matured into the '216 patent). Because a continuation relies on the same disclosure as its parent, it is an effort to obtain additional scope for the patent monopoly based on the same work disclosed in the original specification.

17. After almost three and one-half years of prosecution, the Patent Office allowed claims in the '408 application and issued the '665 patent in January, 1987. The claims of the '665 patent closely resembled the claims of the '216 patent. Specifically, the '665 patent claims (a) processes for cotransforming cells, (b) processes for producing and recovering protein from a cotransformed cell, and (c) cotransformed cells. Because the subject matter of the '665 patent's claims was obvious in view of the '216 patent's broad claims, the Patent Office permitted the '665 patent to issue only after Columbia filed a "terminal disclaimer," disclaiming the part of the patent's term that would have extended past the expiration date of the '216 patent. In this way, although Columbia received additional claims from the Patent Office, it did not obtain any additional time, or "term," in which it could legally exercise its monopoly over the subject matter claimed in the '216 (or '665) patent. Columbia made no attempt to deny that the claims of the '665 patent were obvious in view of the '216 patent.

18. Columbia's effort to obtain additional patents did not end with the '665 patent. In what was to become an oft-repeated tactic, Columbia filed another continuation application, serial no. 06/915,273 ("'273 application"), on October 3, 1986, again based on the specification of the '216 patent (and thus on the same research conducted in the late 1970's), shortly before the then-pending '408 application matured into the '665 patent. In the case of the '273

application, however, Columbia abandoned it after two years of prosecution and filed another continuation, serial no. 07/346,089 ("'089 application"), on May 2, 1989. Columbia then abandoned the '089 application after three years in favor of yet another continuation, serial no. 07/716,915 ("'915 application"), filed on June 18, 1991.

19. By repeatedly filing new applications based on the original specification and research, Columbia has continued, even up to the present, to prosecute claims based on the now decades-old research of Axel, Wigler, and Silverstein. Columbia's practice of "submarine" patenting allowed it to abuse the patent system by "surfacing" with a new patent many years or even decades after filing the original application. Keeping its original specification alive by filing one continuation or divisional application after another, Columbia sought to obtain new patents to capture the latest developments in the biotechnology industry.

20. In the case of the '915 application, which Columbia filed more than a decade after the original 1980 application, Columbia used its submarine patenting strategy to seek and obtain claims covering new advances the biotechnology industry had made during the intervening decade. For example, when Columbia filed the original '513 application in 1980, its researchers did not know that a type of Chinese hamster ovary ("CHO") cells would later be developed which could serve as the preferred host cell for producing desired proteins. Nonetheless, Columbia pursued claims to transformed CHO cells in the '915 application, filed June 18, 1991, and the Patent Office ultimately allowed those claims to issue as the '017 patent. Once again, however, the Patent Office allowed the claims only after Columbia filed a terminal disclaimer limiting the term of the '017 patent to the term of the original '216 patent. Columbia made no attempt to challenge the Patent Office's conclusion that the claims of the '017 patent were obvious in view of the claims already allowed in the '216 and '665 patents. In all, the '216,

'665, and '017 patents contain more than 100 claims, all originating from Columbia's original patent application in 1980.

21. Columbia continued with its submarine patenting strategy. Shortly before the '017 patent issued in January 1993, it filed yet another continuation. Indeed, it ultimately filed ***five*** more continuations based on the original specification describing the early research of Axel and his colleagues. Instead of "surfacing" with a submarine patent, however, Columbia abandoned most of those continuations after desultory prosecution, only to file yet more continuation applications.

22. Effective June 8, 1995, Congress reformed the patent law to close many of the loopholes that had made submarine patenting possible. On June 7, 1995, *the day before this change in the law went into effect,* Columbia secretly filed ***two*** further continuation applications based on the original specification of the '513 application. Under the reform legislation, these two applications were "grandfathered" because they were filed before the change in the law went into effect. In September 2002, one of these applications, serial no. 08/484,136 ("'136 application") issued after numerous amendments as the '275 patent now in suit. Because Columbia did not file a terminal disclaimer with respect to the '275 patent, the patent will not expire until 2019. Yet another application filed the same day as the '136 application, serial no. 08/477,159 ("the '159 application"), is *still pending* at the Patent Office. In this application, Columbia is pursuing claims specifically directed at the commercial products of certain licensees, including products first marketed after the expiration of the '216, '665, and '017 patents.

C. Columbia's '636 Patent

23. At about the same time or shortly after he completed the research on which the original '513 application was based, Axel collaborated with another researcher, James Roberts,

to carry out further research on methods of cotransforming eukaryotic cells with foreign DNA encoding genes for producing desired proteins. Based on this research, which was closely related to the work that had led to the '216, '665, and '017 patents, Columbia filed a separate patent application on March 15, 1982. Columbia eventually abandoned this application, serial no. 358,206 ("'206 application"), in favor of filing a continuation. It repeated this tactic twice more, ultimately receiving U.S. patent 5,149,636 ("'636 patent") on September 22, 1992, more than a decade after it filed the initial '206 application. As discussed more fully below, Columbia never disclosed the '636 patent or its file history to the examiner in the '275 patent prosecution so that he could make a determination of its materiality to the patentability of the '275 patent.

D. Columbia's Licensing of the Axel Patents

24. Columbia granted a non-exclusive license under the '216, '665, '017, and '636 patents (and continuations thereof) to Biogen in 1993. Columbia entered into similar non-exclusive licenses with Genzyme in 1994 and BBC in 1995. Each of the License Agreements provided for up-front royalty payments to Columbia even before plaintiffs brought any product to market. The agreements further provided for minimum annual payments regardless of sales of licensed products. Under the License Agreements, as detailed above in paragraph 10, plaintiffs have paid approximately $60 million to Columbia. Columbia also licensed the patents to other biotechnology companies, reaping hundreds of millions of dollars in royalties.

25. Columbia's license agreements with plaintiffs and other biotechnology companies required the licensees to pay royalties not only on Columbia's issued patents such as the '216 patent, but also on patents issuing from "any and all divisions, continuations and continuations-in-part" thereof. This provision gave Columbia significant incentive to keep spawning "children" of the issued patents, including the '275 patent.

E. Columbia's Failed Attempt to Persuade Congress to Extend Its Patent Monopoly

26. The '216, '665, and '017 patents expired in August, 2000. Shortly before they were due to expire, Columbia embarked on an aggressive lobbying campaign to obtain special legislation from Congress extending the term of the '216 patent. Columbia claimed, among other things, that the income stream from the patent was "absolutely critical" and the "single most important source of free and clear funding" for the university. Notwithstanding the importance of the royalty stream to Columbia, the university claimed that the biotechnology industry was not burdened by paying these royalties, which Columbia characterized as "nominal."

27. During its campaign to persuade Congress to extend the term of the '216 patent, Columbia described its patent as pioneering, and as having great breadth and scope. Columbia represented to Congress that its '216 patent "covers the process for transforming animal cells so they can produce proteins used in biological pharmaceutical products." According to Columbia, it was the '216 patent that "makes it possible to generate the cell lines that are needed to produce patented drugs," specifically identifying Biogen's AVONEX® for treatment of multiple sclerosis and Genzyme's CEREZYME® for treatment of Gaucher's disease as two such drugs. As Columbia told Congress, its patent broadly claimed both "the cotransformed cells and the process of making them."

28. In its submissions to Congress, Columbia requested urgent action on its patent term extension request, representing that "Columbia's cotransformation patent expires on August 16, 2000." Columbia did not tell Congress that Columbia was simultaneously prosecuting secret patent applications that sought the issuance of new patents, with new 17-year terms, claiming the same cotransformation technology. And, just as Columbia did not tell Congress that it was seeking further patent term by pursuing additional continuation applications, Columbia did not

tell the Patent Office what it told Congress, namely, that it believed the '216 patent to have extremely broad claim scope, covering both cotransformed cells and the process of making them.

29. Columbia's request for extension of the term of the '216 patent met with widespread public outcry, and Congress rejected it, recognizing that Columbia had already reaped rich rewards from its seventeen-year patent monopoly. Congress decided that biotechnology companies should not be burdened by paying additional royalties for the period after the expiration of the '216 patent under their licenses with Columbia. Thus, the inventions claimed in the '216, '665, and '017 patents passed into the public domain in August 2000. This meant that plaintiffs, and other biotechnology companies, were free to develop and sell recombinant biological products without the economic burden of paying further royalties to Columbia. Referring to Congress's rejection of Columbia's proposed special legislation, Columbia's spokesperson said, "I do not believe there's a next step in this patent extension story ... it's an issue that's by us. ... Either you get the patent extended or it expires, and there's just no way to go back after it expires, so we're not going to be making any attempt."

F. The Surfacing of the '275 Submarine Patent

30. In fact, however, Columbia had an alternative plan already in place to extend the patent monopoly on its cotransformation technology. As previously set forth, Columbia had in 1995, unbeknownst to its licensees, Congress, or the public, filed two additional patent applications relying on the same patent disclosure and specification that its researchers had made some fifteen years earlier and that had been the basis for the '216, '665, and '017 patents.

31. Since these continuation applications were the last Columbia could file under the pre-reform patent prosecution rules, Columbia could not simply abandon them and further drag out the patent prosecution process as it had done so many times before. If it had filed new continuation applications after June 7, 1995, any patent to issue from those applications would

have expired, under the new rules, in February 2000. Instead, Columbia employed dilatory tactics to keep its June 7, 1995 continuation applications pending, including filing for extensions and filing notices of appeal to gain additional time. These tactics delayed the issuance of additional patents and thereby extended the term of those patents as far as possible into the future.

32. Using these tactics, Columbia strung out the prosecution of the continuation applications to such an extent that one application is still pending eight years after filing and the other did not mature into a patent until more than seven years after its filing date. That patent, the '275 patent, issued on September 24, 2002, almost twenty-three years after the filing of the original specification and more than two years after the expiration of its three earlier cotransformation patents. It was the product of ***eight*** continuing or divisional applications, of which five were abandoned. During prosecution of the '275 patent, which did not even ***begin*** until fifteen years after Columbia filed the original application, Columbia sought extensions of time amounting to some twenty-two months, filed two notices of appeal that it did not pursue, and added many new claims at a late stage in the prosecution.

33. Columbia's dilatory prosecution of the '275 patent and its predecessor applications was not Columbia's only abuse of the patent process. Columbia also resorted to misleading the patent examiner to obtain the patent, as set forth below in paragraphs 50 - 74.

34. Like the '017 patent, the '275 patent purports to claim developments in biotechnology that the Columbia researchers either had not achieved or had been unaware of at the time they filed the '513 application in 1980. Like the '017 patent, the '275 patent claims transformed CHO cells, a cell type that the inventors had never, as of the filing date, used successfully as a vehicle for the production of medically valuable proteins. It also claims

methods of producing and recovering protein materials that the inventors had not successfully practiced as of the time they filed the original '513 application. It also claims a "DNA construct," a term that does not appear in the original specification and came into use in the biotechnology industry only later.

35. Unlike the '017 patent, however, the '275 patent issued ***without any terminal disclaimer.*** Thus, although the discoveries on which it is based had to have been made before the original February 1980 filing date, the '275 patent, were it valid, would remain in effect until ***September 2019.*** In effect, the combined terms of the new patent and the '216 patent run for thirty-six years, from 1983 to 2019 (with a two-year gap between the expiry of the '216 patent and the issuance of the '275 patent). This combined term is far in excess of the limited monopoly contemplated by the Patent Act and would significantly burden the efforts of plaintiffs and other biotechnology companies to develop new innovative recombinant therapeutic and diagnostic products.

G. Columbia's Recent Demand Under the License Agreements

36. Shortly after the '275 patent issued, Columbia announced to Biogen, Genzyme, and other licensees that, contrary to their expectations that royalty payments under the license agreements had come to an end, the issuance of the '275 patent had triggered the obligation to pay royalties under their license agreements once again. For example, by letter to Biogen dated October 3, 2002, Columbia advised Biogen of the issuance of the '275 patent and noted that "Columbia does not agree" that Biogen's last payment was "its last royalty owed." Thus, although plaintiffs believed that their royalty obligations to Columbia had expired with the expiration of the '216, '665, and '017 patents, Columbia was now demanding royalty payments for another seventeen years, the term of the '275 patent.

Claims

Count I: Declaration Under the License Agreements

37. Plaintiffs incorporate all prior paragraphs of this complaint.

38. Columbia contends pursuant to the License Agreements between Columbia and plaintiffs that plaintiffs must pay royalties under the '275 patent. Plaintiffs contend that they have no obligation to pay such royalties because, as set forth below, the '275 patent is invalid and unenforceable. There is an actual controversy between the parties concerning plaintiffs' obligations under the License Agreements.

39. Plaintiffs are entitled to and seek a declaratory judgment that they have no obligation to pay any further royalties under the License Agreements.

Count II: Declaration of Invalidity of the '275 Patent

40. Plaintiffs incorporate all prior paragraphs of this complaint.

41. Plaintiffs are entitled to and seek a declaratory judgment that the '275 patent is invalid for, without limitation, non-statutory obviousness-type double-patenting because each of the claims of the '275 patent is the same as, or merely an obvious variant of, inventions claimed in other patents owned by Columbia, singly or in combination.

42. Plaintiffs are further entitled to and seek a declaratory judgment that the '275 patent is invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and 112.

43. There is an actual controversy between plaintiffs and Columbia concerning the validity of the '275 patent.

Count III: Declaration of Unenforceability of the '275 Patent for Prosecution Laches

44. Plaintiffs incorporate all prior paragraphs of this complaint.

45. Plaintiffs are entitled to and seek a declaratory judgment that the '275 patent is unenforceable by reason of prosecution laches, specifically, Columbia's unreasonable delay in prosecuting the applications that resulted in the '275 patent.

46. There is an actual controversy between plaintiffs and Columbia concerning the enforceability of the '275 patent.

Count IV: Declaration of Unenforceability of the '275 Patent for Inequitable Conduct

47. Plaintiffs incorporate all prior paragraphs of this complaint.

48. Plaintiffs are entitled to and seek a declaratory judgment that the '275 patent is unenforceable by reason of inequitable conduct, specifically, as set forth below, Columbia's (a) advancing misleading statements to the examiner about whether its claims were patentable, (b) failure to make timely disclosure of a related application and its prosecution history, (c) failure to disclose the '636 patent and its prosecution history, and (d) failure to disclose statements it had made to Congress that were inconsistent with positions it took during prosecution of the '275 patent.

49. There is an actual controversy between plaintiffs and Columbia concerning the unenforceability of the '275 patent for inequitable conduct.

A. Misleading Statements Regarding the Patentability of Claims of the '275 Patent

50. As previously set forth, Columbia held three patents that all relied upon the same original disclosure and that expired in August, 2000: the '216, '665, and '017 patents. To overcome double-patenting rejections, Columbia filed terminal disclaimers that ended the term of the '665 patent and the '017 patent on the expiration date of the '216 patent.

51. During prosecution of the '275 patent, in an office action dated February 3, 1998, the examiner rejected all pending claims for double patenting over the issued claims of the '017 patent. These rejected claims, then numbered 126-132, were drawn to DNA constructs for

transforming cells and, in the case of claim 132, eukaryotic cells transformed using such constructs.

52. In response to the February 3, 1998 office action, on July 24, 1998, Columbia canceled claim 132, the only claim to transformed eukaryotic cells then pending. Columbia also argued that the remaining DNA construct claims were not subject to double-patenting rejection over the '017 patent. Columbia stated: "The 'right to exclude' provided by claims 1-4 of U.S. 5,179,017 relates to transformed Chinese Hamster Ovary (CHO) cells. Thus, the 'right to exclude' provided by U.S. 5,179,017 relates only to the manufacture, use and sale of CHO cells. In contrast, the 'right to exclude' which would be provided by claims 126-131 of the subject application would, if allowed, relate to the manufacture, use and sale of DNA constructs." July 24, 1998 Response, pp. 2-3 (emphasis in original). Thus, Columbia acknowledged that the claims that issued in the '017 patent relate to transformed CHO cells.

53. During prosecution of the '275 patent, in an amendment filed June 14, 2001, Columbia added numerous new claims, some of which ultimately issued in the '275 patent. The Remarks accompanying this amendment stated that the new claims were "not subject to the obviousness-type double-patenting rejection." It then listed the claims in groups and explained why each group was not subject to rejection on double-patenting grounds. In each case, however, Columbia presented argument only about why the claims were not subject to double-patenting in view of the '216 patent, not the '017. Because the claims about which Columbia presented these arguments were newly submitted, Columbia did not make its assertions about double-patenting in response to an examiner's rejection of claims; rather, Columbia made these statements preemptively, to deter the examiner from issuing double-patenting rejections. By this

time, a new examiner, who had not been involved in the double-patenting rejections in February 1998, was now assigned to the case.

54. In asserting that the new claims in the '136 application (which led to the '275 patent) were not subject to double-patenting rejections over the '216 patent, Columbia misled the Patent Office by failing to draw the new examiner's attention to the claims of Columbia's other patents, and most significantly the '017 patent. The claims of the '017 patent, which provided the basis for double patenting rejections in 1998 by the examiner at that time, are substantially similar to the new claims Columbia added to the '136 application in June 2001 and could have provided a basis for a double-patenting rejection of the new claims.

55. Columbia's statement that the new claims should not be rejected over the '216 patent, while failing to draw the examiner's attention to grounds for rejection over the '017 patent, was misleading because it implied that the '216 patent was the only basis upon which a double patenting rejection could be made. Moreover, in view of Columbia's statements in the July 24, 1998 Response conceding that the '017 patent relates to transformed CHO cells, Columbia was aware that the newly asserted claims, many of which were directed to transformed CHO cells, were vulnerable to double-patenting rejections over the '017 patent claims. Given the facts recited above, it is reasonable to infer that Columbia's misleading omission of Columbia's other issued patents, particularly the '017 patent, from its preemptive argument to the new examiner was a deliberate and intentional effort to draw attention away from the other grounds on which the claims could be rejected for double-patenting and thus to mislead the examiner.

56. Moreover, the very arguments that Columbia raised to head off double patenting rejections of the newly added claims were themselves substantially false and misleading. For

example, Columbia stated that certain of the new claims were not vulnerable to double patenting rejections because "none of the claims of the '216 make obvious a recitation of 'linked' [DNA I and DNA II]." In fact, issued claim 54 of the '216 patent recites transforming a eucaryotic cell "with a molecule which is ***formed by linking*** one of said foreign DNA I molecules to a DNA II molecule."

57. As another example, Columbia stated that other of the newly added claims were not vulnerable to double patenting rejections because "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified." However, issued claim 54 of the '216 patent (for example) recites transforming cells with a molecule formed by ***linking*** a DNA I to an ***amplifiable*** DNA II, and culturing the transformed cells under conditions "permitting survival or identification of eucaryotic cells which have acquired multiple copies of said amplifiable gene." Because DNA II is an amplifiable gene linked to DNA I, it is inherent in the claim that the end result is both amplified DNA I and amplified DNA II. Therefore, contrary to Columbia's assertion, claim 54 does indeed make obvious a recitation that both DNA I and DNA II are amplified.

58. In an office action on the '136 application dated July 30, 2001, the examiner rejected a number of the newly added claims for, among other things, obviousness-type double-patenting over claim 73 of the '216 patent.

59. In response to this office action, in a paper filed January 30, 2002, Columbia again stated that the claims were not obvious in view of the '216 patent for the same reasons it had asserted in its June 14, 2001 amendment. Like the June 14, 2001 amendment, the January 30, 2002 paper made no mention of the '017 patent or the fact that the claims of the '017 patent were substantially similar to the claims Columbia was then seeking.

60. Like the June 14, 2001 Remarks, Columbia's January 30, 2002 statement that the new claims should not be rejected over the '216 patent, while failing to draw the examiner's attention to grounds for rejection over the '017 patent, was misleading because it implied that the '216 patent was the only basis upon which a double-patenting rejection could be made. Upon information and belief, Columbia presented these statements with intent to mislead the patent examiner. The '275 patent is therefore unenforceable due to inequitable conduct in its prosecution.

B. Failure to Disclose Rejection of Substantially Similar Claims in '159 Application

61. As set forth in paragraph 22 above, on June 7, 1995, Columbia filed two continuation applications relying on the original disclosure filed in February 1980. One of these applications matured into the '275 patent. The other, serial no. 08/477,159 ("the '159 application"), is still pending today.

62. The '159 application included claims directed to subject matter that is substantially similar to the subject matter claimed in the '275 patent. For example, claim 135 of the '159 application was substantially similar to issued claim 14 of the '275.

63. On April 22, 1997, the examiner then assigned to the '159 application issued an office action rejecting claims in the '159 application for double patenting over the '017, '216, and '665 patents, including claim 135. The claims were also rejected for failure to satisfy 35 U.S.C. § 112. Because these claims are substantially similar to claims that issued in the '275 patent, these rejections are highly material to the patentability those claims.

64. Despite the materiality of the '159 application and the rejections of claims substantially similar to the '275 claims in April 1997, Columbia did not make the existence of the '159 application of record in the '275 prosecution until May 6, 2002, nearly ***seven years*** into the co-pendency of the two applications and a mere three months before allowance of the claims

of the '275 patent. Even then, Columbia failed to disclose to the examiner the prior double-patenting rejections, by a different examiner in the '159 prosecution, of claims substantially similar to those in the '275 application. This contrary decision by another examiner was material to the patentability of the '275 claims.

65. Given the facts recited above, it is reasonable to infer that Columbia's unreasonable delay in disclosing the '159 application, as well as its failure to disclose the rejection of substantially similar claims by a different examiner in that case, was deliberate and intentional. Therefore, the '275 patent is unenforceable due to inequitable conduct in its prosecution.

C. Failure to Disclose '636 Patent and Rejection of Substantially Similar Claims

66. As previously set forth, Columbia's '636 patent, which issued in 1992, was pending during the prosecution of several of the submarine applications that ultimately led to the '275 patent. The claims of the '636 patent include claims directed to (a) processes for generating multiple copies of a foreign DNA I in eukaryotic cells and (b) product claims directed to eukaryotic and mammalian cells into which foreign DNA I has been introduced by the claimed processes. These product-by-process claims of the '636 patent overlap in scope with at least claim 5 of the '275 patent and its dependent claims. The '636 patent was prosecuted by the same law firm that prosecuted the '216 patent and its continuations and divisional applications (along with foreign counterparts, "'216 patent family"), including the '275 patent.

67. Columbia never disclosed the '636 patent to the examiner or made it of record during the prosecution of the '216 patent family, despite the fact that the '636 patent could have provided a basis for a double patenting rejection of various claims in the numerous applications that led to the '275 patent. Thus, the existence of the '636 patent was material to the

patentability of claims Columbia prosecuted in the '216 patent family, including at least one claim that issued as part of the '275 patent.

68. The '636 file history includes rejections of claims that are substantially similar to claims pursued during prosecution of the '216 patent family, including the '275 patent. For example, in application 06/683,251, the second application in the chain that led to the '636 patent, Columbia pursued two claims, 24 and 25, that are substantially similar to issued claim 5 of the '275 patent. In an office action dated June 3, 1986, the examiner rejected these claims as anticipated by or obvious in view of the '216 patent or a related published international application. Undaunted, Columbia pursued these same claims in application 07/103,807, the third application in the chain leading to the '636 patent. They were again rejected, on the same grounds, in an office action dated March 24, 1988. These rejections evidence the closeness between the '216 patent family (which includes the '275 patent) and the claims Columbia was seeking in prosecuting the '636 patent. Thus, it is highly likely that a patent examiner evaluating the claims proposed in the applications leading up to the '275 patent would have wanted to be informed of the rejection, by a different examiner, of claims pursued in prosecution of the applications leading up to the '636 patent. Those rejections are therefore material to the patentability of the claims asserted during the prosecution of the '216 patent family, including the claims that ultimately issued in the '275 patent.

69. Notwithstanding the more than ***twenty years*** between the filing of the application that led to the '636 patent and the issuance of the '275 patent, and the many information disclosure statements Columbia filed in the prosecution of the '216 patent family during that time period, Columbia failed to make the pendency, the issuance, or any part of the file history of the '636 patent of record in any of the applications that led to the issuance of the '275 patent.

70. As the owner of the '636 patent as well as the '275 patent, Columbia was aware of the materiality of the '636 patent and its file history to the '275 patent, as was its patent counsel, who prosecuted both the '636 and the '275 patents. Given the singular commercial and financial importance of the '216 patent family, it is reasonable to infer that Columbia's strategy for prosecuting that patent family and, in particular, the applications leading up to the '275 patent, did not arise from inattentiveness or accident. Given the facts recited above, it is also reasonable to infer that Columbia's failure to disclose the '636 patent or its file history during the prosecution of the '216 patent family was deliberate and intentional. Therefore, the '275 patent is unenforceable due to inequitable conduct in its prosecution.

D. Failure to Disclose Statements to Congress Inconsistent With Positions Taken Before the Patent Office

71. As previously set forth in paragraphs 26 - 29, as the expiration date of the '216, '665, and '017 patents loomed, Columbia undertook a lobbying campaign in an attempt to secure from Congress an extension on its monopoly over the technology claimed in the '216 patent. In the course of that campaign, Columbia made numerous statements to Congress that were inconsistent with positions it took in its concurrent prosecution of the '275 patent claims in the Patent Office. In its statements to Congress, Columbia emphasized the breadth and pioneering scope of the '216 patent. Indeed, Columbia told Congress that its patent broadly claimed both "cotransformed cells and the process of making them." In its statements to the Patent Office, on the other hand, Columbia argued that the scope of the '216 patent was much more limited. Columbia never disclosed to the Patent Office during prosecution of the '275 patent the inconsistent representations it made to Congress in 2000, in violation of its duty of candor to the Patent Office under 37 C.F.R. § 1.56.

72. Columbia also made inconsistent representations to Congress and the Patent Office on narrower issues. For example, Columbia told Congress that the '216 patent covered both what is known as "linked" cotransformation as well as what is known as "unlinked" cotransformation. With respect to linked cotransformation, Columbia told Congress that under the '216 patent, "[t]he genes of interest can be joined together in a single DNA construct prior to their introduction into the cell of interest." Columbia also asserted to Congress that "[t]he Cotransformation process [claimed in the '216 patent] permit[s] the ... amplification of the gene of interest for the purpose of expressing large amounts of the protein it encoded."

73. In prosecuting the '275 patent, by contrast, Columbia characterized the claims of the '216 patent far more narrowly. For example, as set forth above in paragraph 56, Columbia stated, in June 14, 2001 and January 30, 2002 responses to office actions, that "none of the claims of the '216 make obvious a recitation of 'linked' [DNA I and DNA II]." Columbia also stated that "none of the claims of the '216 make obvious a recitation that both DNA I and DNA II are amplified." These statements were made to avoid obviousness-type double-patenting rejections over the '216 patent and were meant to persuade the examiner to read the '216 patent's claims with a narrow scope.

74. Thus, Columbia's assertions to Congress of the sweeping breadth of the '216 patent directly contradict its exhortations to the examiner of the '275 patent to read the '216 patent narrowly. Columbia never disclosed its statements to Congress to the Patent Office or advised the examiner that it had ever taken contrary positions as to the scope of the '216 claims. It may reasonably be inferred from these facts that Columbia's omission to disclose these inconsistent statements to the Patent Office was deliberately misleading. The '275 patent is therefore unenforceable for inequitable conduct.

Count V: Declaration of Exceptional Case

75. Plaintiffs incorporate all prior paragraphs of this complaint.

76. Plaintiffs are entitled to and seek a declaratory judgment that this is an exceptional case under 35 U.S.C. § 285 and that they are entitled to an award of reasonable attorneys' fees, costs, and expenses.

Requests for Relief

For the reasons set forth above, and for such other reasons that may be presented at trial, plaintiffs seek the following relief:

A. Judgment for plaintiffs against Columbia on all counts of this complaint;

B. Declarations that plaintiffs have no obligation to pay further royalties to Columbia under the License Agreements;

C. Declarations of invalidity and unenforceability of the '275 patent on the grounds set forth above;

D. Preliminary injunctive relief prohibiting the enforcement of the License Agreements during the pendency of this action;

E. Permanent injunctive relief prohibiting Columbia from demanding any further royalties under the License Agreements based on the '275 patent or on any pending continuations, continuations-in-part, or divisional applications of the patents recited in those agreements;

F. A declaration that this is an exceptional case under 35 U.S.C. § 285;

G. An award of reasonable attorneys' fees, costs, and expenses; and

H. Such other or further relief that the Court deems just.

Dated: August 21, 2003

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